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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,765	01/14/2004	Per Egnelov	030481-0212	1510
22428	7590	09/19/2005	EXAMINER	
FOLEY AND LARDNER				MALLARI, PATRICIA C
SUITE 500				ART UNIT
3000 K STREET NW				PAPER NUMBER
WASHINGTON, DC 20007				3736

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/756,765	EGNELOV ET AL.
	Examiner Patricia C. Mallari	Art Unit 3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 June 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3-16 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 9-16 is/are allowed.
- 6) Claim(s) 1,3-8 and 20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 14 January 2004 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/14/04</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

This is a final Office action. Any new grounds of rejection were necessitated by the applicants' amendment to the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 3, 4, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 3,730,168 to McWhorter. McWhorter teaches an indicator device for visually indicating a pressure of blood inside a blood vessel comprising a body, an insertion tube 18, and a window (fig. 1; col. 3, lines 6-46 of McWhorter). The body comprises a passage 16 passing through the body and further comprising a duct 12a and having a hemostatically sealed blood accommodating chamber 11a (fig. 1; col. 3, lines 10-23 of McWhorter). The insertion tube 18 comprises a distal end portion adapted to be positioned inside the blood vessel and comprising a fluid communication pathway between a liquid inlet opening at the distal end of the insertion tube 18 (col. 3, lines 11-21 of McWhorter). The window comprises an at least semi-transparent section configured to enable visual observation of blood entering into the duct 12a via the inlet opening at the distal end of the insertion tube when the inlet opening is located inside the blood vessel (col. 3, lines 40-47 of McWhorter). The applicants should further note that figure 1 shows the needle or insertion tube and body 17 being aligned such that a

member would be capable of being threaded therethrough in a substantially straight path between the distal and proximal ends of the indicator device.

As to the language "for visually indicating a pressure of blood inside a blood vessel, " "blood accommodating," "adapted to be positioned inside the blood vessel," and "to enable visual observation of blood entering into the duct via the inlet opening when the inlet opening is located inside the blood vessel," the applicants should note that this is merely "intended use" language which cannot be relied upon to define over the prior art, since McWhorter teaches all of the claimed elements and their recited relationships. See *Ex parte Masham* 2 USPQ 2nd 1647. The chamber of McWhorter is fully capable of accommodating blood. The insertion tube of McWhorter is similarly capable of being positioned within a blood vessel such that device indicates blood pressure. Additionally, the window of McWhorter would be capable of enabling visual observation of blood entering the duct when the inlet opening is located inside the blood vessel.

Regarding claim 3, the duct 12a opens into the chamber 11 via an aperture having a spill-over edge 15, the aperture being located at a level above a bottom surface of the blood accommodating chamber 11, whereby return flow of the blood back into the duct 12a is prevented (fig. 1 of McWhorter).

Regarding claim 4, wherein the blood accommodating chamber 11 is located in the body, and the body further comprises the insertion tube 18 extending distally of the body (fig. 1 of McWhorter)

Regarding claims 6 and 7, the duct 12a extends vertically or horizontally to an aperture opening in to the blood accommodating chamber 11 (fig. 1 of McWhorter), depending on how the device as a whole is held or oriented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over McWhorter, as applied to claims 1, 3, 4, 6, and 7 above, and further in view of US Patent No. 2,748,769 to Huber. McWhorter discloses the insertion tube as a needle inherently having an opening somewhere along the distal end to enable fluid to enter the needle 18 (col. 3, lines 11-21; col. 3, lines 25-39 of McWhorter), but fails to give details as to the needle. However, Huber teaches a hypodermic needle adapted to be positioned inside a blood vessel and comprising a fluid communication pathway 10 and a liquid inlet opening 16, wherein the opening 16 is located on a side of the needle (figs. 1-5; col. 2, lines 46-57 of Huber). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the needle of Huber as that of McWhorter, since McWhorter teaches using a needle and Huber describes an appropriate such needle.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over McWhorter, as applied to claims 1, 3, 4, 6, and 7 above, and further in view of US

Patent 3,062,202 to Hyman et al. McWhorter teaches the duct 12a being uniform in cross section over its length (fig. 1 of McWhorter) rather than having a varying cross-section over its length. However, Hyman discloses that the cross section of a duct of a pressure indicating device may be varied over its length or may be uniform in cross section (col. 3, lines 19-31 of Hyman). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to vary the cross section over the length of the duct of McWhorter in order to provide different sensitivities at different pressure ranges (col. 3, lines 28-31 of Hyman).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over McWhorter, as applied to claims 1, 3, 4, 6, and 7 above, and further in view of Hyman et al. McWhorter teaches providing an indicator device for visually indicating the pressure of a bodily fluid within the body, but fails to describe steps of measuring blood pressure using the device (col. 1, lines 46-50; col. 3, lines 37-44 of McWhorter). However, Hyman teaches a device 10 suitable for visually indicating the pressure of a bodily fluid, wherein such pressure includes blood pressure or spinal fluid pressure (col. 2, lines 9-19 of Hyman). The indicator device 10 is provided, and the distal end portion of the device is positioned inside the blood vessel (col. 2, lines 35-40 of Hyman). The pressure is then indicated (figs. 1 & 2; col. 2, lines 40-47 of Hyman). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the method of Hyman to measure blood pressure with the device of McWhorter, since McWhorter teaches a device that can be used for measuring the pressure of a bodily fluid within the body, and Hyman teaches an appropriate method of doing so.

Response to Arguments

Applicant's arguments with respect to claims 1-8 and 20 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

Claims 9-16 are allowed. The allowability of the claims was addressed in a previous Office action filed 4/20/05.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571)

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272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Mallari
Patricia Mallari
Patent Examiner
Art Unit 3736

Robert L. Nasser
ROBERT L. NASSER
PRIMARY EXAMINER